

1 Adopt 17 Cal. Code of Regs. section 100085 to read:

2 **§ 100085. Use of Fetal Tissue.**

3 Fetal tissue shall be procured in accordance with 17 Cal. Code Regs. section 100080,
4 subdivisions (e)(1)-(3). In addition research involving human fetal tissue will adhere to the
5 following provisions:

6 (a) The woman who donates the fetal tissue must sign a statement declaring:

7 (1) That the donation is being made for research purposes, and

8 (2) The donation is made without any restriction regarding the identity of individuals
9 who may be the recipients of materials derived from the tissue; and .

10 (b) The attending physician must:

11 (1) Sign a statement that he/she has obtained the tissue in accordance with the donor's
12 signed statement.

13 (2) Disclose to the donor any financial interest that the attending physician has in the
14 research to be conducted with the tissue.

15 (3) Disclose any known medical risks to the donor or risks to her privacy that might be
16 associated with the donation of the tissue and that are in addition to risks of such type that are
17 associated with the woman's medical care.

18 (4) In the case of tissue obtained pursuant to an induced abortion, the physician must sign
19 a statement stating that he/she obtained the woman's consent for the abortion before requesting
20 or obtaining consent for the tissue to be used for research; did not alter the timing, method, or
21 procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for
22 research; and performed the abortion in accordance with applicable state and local laws.

1 (c) The principal investigator of the research project must sign a statement certifying that
2 he/she is aware that the tissue is human fetal tissue obtained in a spontaneous or induced
3 abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The
4 principal investigator must certify in writing that he/she has had no part in any decisions as to the
5 timing, method, or procedures used to terminate the pregnancy and he/she is not the donor's
6 attending physician.

7 Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j),
8 Health and Safety Code.

9 Reference: Sections 125290.35, 125290.40, 125290.55, 125300, Health and Safety Code.